

**REMARKS**

Claims 1 to 3, 5 to 10, and 13 to 17 are pending in the application.

Claims 1 to 3, 5 to 8, and 13 to 16 are currently amended.

Claims 4, 9 to 12, and 17 are cancelled.

Claim 18 is new.

Claims 1 to 3, 5 to 8, 13 to 16, and 18 would be all of the claims pending in the application if the amendment in this paper is entered.

***Discussion of Amendments***

Support for the amendments to Claims 1 to 3, 5 to 8, and 13 to 16 is found in the specification, including, but not limited to, page 20, at line 1, and the original claims as filed.

Applicant believes that the subject matter of the above claim listing is within the subject matter of the elected invention. Applicant retains all rights to reintroduce cancelled or deleted subject matter in the claims in the present application or in any continuation, divisional, and continuation-in-part applications thereof.

***Claim Objections***

The amendment filed January 22, 2004, is objected to under 35 U.S.C. § 132 because it allegedly introduces new matter into the disclosure. In the amendment filed January 22, 2004, the phrase “wherein the compound isophthalic acid bis-(1,3-benzodioxol-5-ylmethyl) ester is excluded” was introduced into Claims 1, 2, and 5. The Examiner alleged that the original claims and specification do not provide antecedent basis for the introduction of the phrase into these claims, and required Applicants to cancel the alleged new matter in the reply to the Office Action.

Applicants respectfully traverse this objection on the basis of a holding in *In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977). There the court stated:

“The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.” (194 U.S.P.Q. 196)

Applicants believe that *In re Johnson* stands for the proposition that it is improper to object to or reject a claim to a genus minus a reasonable number of species within that genus, including species not specifically described in the specification, for lack of written description when the specification has adequate written description for the genus and species within that genus.

In the amendment filed January 22, 2004, Claims 1, 2, and 5 each use a different genus minus the compound no. 0013 of JP-405193260. The JP-405193260 compound no. 0013 was the basis for a rejection of Claims 1, 2, and 5 under 35 U.S.C. 102 in a previous office action. Applicants' amendment and response filed on January 22, 2004, excluded compound no. 0013 of JP-405193260.

The specification on page 3, at line 8, to page 4, at line 7, and on page 5, at lines 4 to 11, describes the genera used in original Claims 1, 2, or 5 (i.e., the genera without any species excluded), respectively. Preparation and use of the compounds used in original Claims 1, 2, and 5 is described on pages 27 to 46.

Further, a number of species that fall within the genera of Claims 1, 2, and/or 5 are described in Examples 3, 5, 14, 19, 22, 28, 37, 45, 46, 49, and 65 to 69 of the specification.

Applicants believe that the genera of original Claims 1, 2, and 5 and the species of the above-referenced examples are described in the specification in such a manner as to disclose to and teach those skilled in the art how to make and use the genera minus the compound no. 0013 of JP-405193260 that was previously cited by the Examiner. Accordingly, Applicants believe that Claims 1, 2, and 5 as amended in the amendment dated January 22, 2004, do not contain new matter, and that the objection under 35 U.S.C. § 132 should be withdrawn.

#### ***Claim Rejections - 35 U.S.C. § 112***

Claims 1, 2, and 5 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleged that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Claims 1, 2, and 5 in the amendment dated January 22, 2004, are different than the original specification as filed because the phrase “wherein the compound isophthalic acid bis-(1,3-benzodioxol-5-ylmethyl) ester is excluded” was introduced in Claims 1, 2, and 5 by the amendment dated January 22, 2004. The Examiner alleged that the original claims and specification do not provide antecedent basis for this amendment.

Applicants respectfully traverse this objection on the basis of the above-referenced holding in *In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977). For the reasons provided above, Applicants believe that the genera used in original Claims 1, 2, or 5 and the species of the above-referenced examples are described in the instant specification in such a manner as to disclose to and teach

those skilled in the art how to make and use the genera minus the compound no. 0013 of JP-405193260 that was previously cited by the Examiner. Accordingly, Applicants believe that Claims 1, 2, and 5 as amended in the amendment dated January 22, 2004, are patentable under 35 U.S.C. § 112, first paragraph, and that the rejection should be withdrawn.

Claims 1 to 3, 5, 6, 8 to 10, and 13 to 17 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, “while being enabling for inhibiting matrix metalloproteinase enzymes, such as MMP-13 in an animal by administering to the mammal the compound of formula I for any known disease.” The Examiner alleged that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant respectfully traverses the rejection on the grounds that Claims 9, 10, and 17 are cancelled, rendering rejection of Claims 9, 10, and 17 moot, and that Claims 1 to 3, 5, 6, 8, and 13 to 16 are enabled for reasons provided below.

Table 1 of the specification on pages 48 to 50 teaches that the compounds of the claimed invention are inhibitors of MMP-13 catalytic domain. A skilled artisan would thus know that these compounds are inhibitors of full-length MMP-13, as it was known from Ye Qi-Zhuang, Hupe D., Johnson L., *Current Medicinal Chemistry*, 1996;3:407-418 that inhibitor activity against a catalytic domain of an MMP is predictive of the inhibitor activity against the respective full-length enzyme.

Claims 1 to 3, 5, 6, and 13 to 16 relate to treating breast carcinoma, rheumatoid arthritis, osteoarthritis, or heart failure. As the Examiner stated on page 5 of the Office Action:

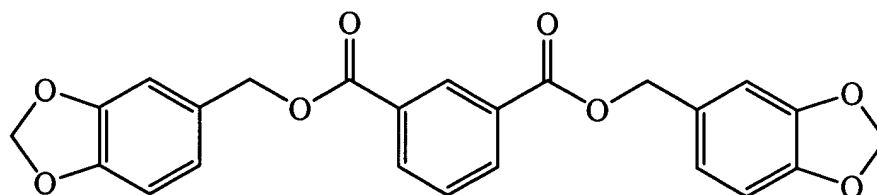
“MMP inhibitors have been used to prevent and treat congestive heart failure and other cardiovascular diseases and that MMP-13 has been over expressed in breast carcinoma.”

Further, Applicants believe the over activity of MMP-13 had been correlated with rheumatoid arthritis and osteoarthritis at the time the application was filed. For example, see (a) Neuhold et al., J. Clin. Invest., 2001;107(1):35-44 (b) Lovejoy et al., Nature Structural Biol., 1999;6:217-221; (c) Moy et al., J. Mol. Biol., 2000;302:671-689; (d) Mitchell et al., J. Clin. Invest., 1996;97(3):761-768; (e) Dahlberg et al., Arthrit. & Rheum., 2000;43(3):673-682; (f) Billingham et al., Arthrit. & Rheum., 2000;43(3):664-672; and (g) Billingham et al., J. Clin. Invest., 1997;99(7):1534-1545, copies of which are provided with the enclosed Supplemental Information Disclosure Statement.

Applicant believes that when the invention is taken as a whole in view of the state of the art at the time the present application was filed, a skilled artisan would expect that the invention of Claims 1 to 3, 5, 6, 8, and 13 to 16 is enabled and patentable under 35 U.S.C. § 112, first paragraph.

#### ***Claim Rejections - 35 U.S.C. § 102***

Claims 1, 2, and 5 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by JP-405193260. The Examiner alleged that the reference compound no. 0013, drawn below, anticipates the claims:



Applicants traverse the rejection on the grounds that the reference compound is excluded from Claims 1, 2, and 5.

***Supplemental Information Disclosure Statement***

Applicant herewith makes available to the Patent and Trademark Office a Supplemental Information Disclosure Statement on forms PTO/SB/08A and/or PTO/SB/08B and copies of the art cited thereon except any U.S. patent or patent application publication documents.

Applicant respectfully requests that the Examiner consider carefully the complete text of the cited reference(s) in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a).

It is respectfully requested that all cited reference(s) considered by the Examiner be listed in the "References Cited" portion of any patent issuing from the instant application (MPEP § 1302.12).

***Conclusion***

In view of the above amendments and remarks, Applicant believes that the objection to Claims 1, 2, and 5, the rejection of Claims 1, 2, and 5 under 35 U.S.C. § 112, first paragraph, the rejection of Claims 1 to 3, 5, 6, 8 to 10, and 13 to 17 under 35 U.S.C. § 112, first paragraph, and the rejection of Claims 1, 2, and 5 under 35 U.S.C. § 102(b) have been overcome. Applicant respectfully requests reconsideration of Claims 1 to 3, 5 to 8, and 13 to 16, and consideration of new Claim 18.

The undersigned would welcome a telephone call from the Examiner to discuss any matters related to this case that the Examiner thinks are amenable to resolution by such discussion.

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Respectfully submitted,

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